REMARKS

Claims 1, 3, 4-6, 9, 11, 18, 25, 26, and 38 have been amended, and claims 42-76 have been added to claim embodiments as described in Applicants' specification. Support for the amendments is found in the specification and claims as filed, *e.g.*, paragraph 97, 101, 103, and 104 of the specification, and FIGs. 1, 6 and 8. Claims 2, 7-8, 10, 20, 22-24, 27-28, 30-32, 34-37, and 40 have been cancelled without prejudice or disclaimer. Accordingly, claims 1, 3-6, 9, 11-19, 21, 25-26, 29, 33, 38-39, and 41-76 are now pending in the case. No new matter has been added.

35 U.S.C. §102

Claims 1, 3-6, 9, 18, 22, 24-26 and 29 were rejected under 35 U.S.C. §102(b) as anticipated by Webber U.S. Patent No. 6,081,577 ("Webber", or " '577 "). The rejection is moot as to canceled claims 22 and 24. As to the other claims, Applicants respectfully traverse.

Claim 1, as amended, relates to a method including obtaining a first image(s) of a body part in a first plane, wherein the first image(s) generates a first image data volume; obtaining a second image(s) of the body part in a second plane, wherein the second image(s) generates a second image data volume; extracting boundary image data from each of the first and second image data volumes; and combining the extracted boundary image data to form a resultant boundary data volume.

The method of the embodiments presently claimed in claim 1 and, by extension, its dependent claims, is not anticipated by Webber. Fig. 33 and column 21 are respectfully submitted to be representative of the methods taught in Webber. Webber, as the Examiner correctly noted at the top of page 8 of the

Office Action, is silent as to extraction of boundary image data from image data volumes, much less following that with combining of the resultant boundary image data to obtain a resultant boundary data volume, as required by Applicants' amended claims.

Claim 25, as amended relates to methods including obtaining at least one image of a body part in at least a first plane and a second plane, wherein the first plane generates a first image data volume and the second plane generates a second image data volume; combining the first and second image data volumes to form a resultant, near-isotropic or isotropic, image data volume; and using the resultant image data volume to derive an implant shape. The embodiment claimed in amended claim 25 is not anticipated by Webber, because Webber does not teach obtaining a near-isotropic or isotropic image data volume as claimed, followed by deriving an implant shape from the resultant near-isotropic image data volume as claimed. Withdrawal of the rejection is respectfully requested.

Amended claim 18 relates to methods for treating a body part, including acquiring at least two data volumes from at least two body part images performed in two different planes; combining the data volumes to form a resultant data volume; and deriving a therapy for the body part using the resultant data volume. The embodiment claimed in amended claim 18, and its dependents, is not anticipated by Webber. Webber does not teach acquiring at least two data volumes as claimed, followed by deriving a therapy for the body part using the resultant data volume. Webber in particular does not teach or suggest deriving a therapy for a body part; in passing, Applicants note that the section of Webber cited by the Examiner as "monitoring a therapy utilizing the resultant data volume":

> "Additionally, the three-dimensional representation can be displayed using the display device depicted in FIG. 28 in order to produce a holographic-type display. The display device comprises a pair of stereoscopic eyeglasses or spectacles 1080 which are worn by an observer 1082. The eyeglasses 1080 contain lenses which are either cross-polarized or which pass complementary colored light. In addition, a target 1084 is positioned on the eyeglass frame 1080. A color computer monitor 1086 and video camera or detector 1088 are provided in association with the eyeglasses 1080. The color monitor 1086 is used to display complementary-colored or cross-polarized stereoscopic image pairs 1090 of the three-dimensional representation. The video camera 1088 is used to track the target 1084 as the observer3 s head is moved. When the observer's head is moved to a different position, the video camera 1088 relays information either directly to the color monitor 1086 or to the color monitor 1086 through computer-related hardware. The information relayed by the video camera relates to the angle subtended by the target 1084 relative to the video camera 1088. The relayed information is then used to alter the angular disparity associated with the stereoscopic image pairs 1090 being displayed on the color monitor 1080 in quasi-realtime, so that the resulting display is adjusted to correlate with the movement of the observer's head and appears holographic to the observer."

in fact has nothing to do with therapy, as a plain reading of that text reveals. Accordingly, withdrawal of this rejection is respectfully requested.

Amended claim 26 claims a method for treating a body part including acquiring at least a first data volume and a second data volume from at least a first body part image and a second body part image, wherein the first body part image is obtained in a first plane and the second body part image is obtained in a second plane and further wherein the first plane is not equal to the second plane; extracting boundary image data from each of the data volumes; combining the extracted boundary image data to form a resultant boundary data volume;

deriving the three-dimensional shape of the body part from the resultant boundary data volume; and selecting a therapy utilizing the three-dimensional shape information. Webber does not anticipate claim 26 and its dependents, since it provides no teaching or suggestion of extracting boundary image data from each of the claimed data volumes, combining the extracted boundary image data to form a boundary data volume, and deriving the three-dimensional shape of the body part from the boundary data volume; then selecting a therapy utilizing the 3-D shape information. Also - as noted above - Webber does not contemplate any therapy based on the information obtained by Webber's disclosed methods. Applicants note the Examiner's citation of Aylward et al. in combination with Webber for other claims reciting boundary image data extraction. Aylward will be discussed in more detail below, but Applicants wish to note here that Aylward does not teach or suggest extracting boundary image data from data volumes as claimed, combining the extracted boundary image data to form a boundary data volume, and deriving the three-dimensional shape of a body part from that boundary data volume.

So, as particularly argued above, Webber cannot anticipate the presently claimed embodiments, and withdrawal of the rejection is submitted to be in order and is respectfully requested.

35 U.S.C. §103

Claims 2, 19 and 27 were rejected under 35 U.S.C. §103(a) as unpatentable (obvious) over Webber, in view of Thesen et al. U.S. Patent No. 6,556,855 ("Thesen", or " '855 "). The rejection is moot as to canceled claims 2 and 19. As to still-pending claim 19, Applicants respectfully traverse. Amended claim 18, from which claim 19 depends, recites a method for treating a body part, where

ultimately a therapy is derived for the body part via the acquisition and combination steps as claimed. One of ordinary skill in the art would not find either reference useful in arriving at the claimed invention; as noted above, Webber does not contemplate any therapy based on the information obtained by Webber's disclosed methods; and Thesen, which is a technically-minded disclosure very specifically directed towards method for the implementation of a perfusion measurement with magnetic resonance imaging, adds nothing to Webber, either. As such, Applicants respectfully submit that the claimed invention is not obvious as urged by the Examiner, and request withdrawal of the rejection.

Claims 7, 8, 10-17, 20, 21, 23, 28 and 30-33 were rejected under 35 U.S.C. §103(a) as unpatentable (obvious) over Webber, in view of Aylward et al. U.S. Patent No. 6,690,816 ("Aylward", or " '816 "). The rejection is moot as to canceled claims 7-8, 10, 20, 23, 28 and 33. As to still-pending claims 11-17, 21, and 33, Applicants respectfully traverse in view of the amendments made herein, and comments which follow.

Claim 11, as amended, recites a method for designing an implant for a body part, including obtaining a first image data volume from a first image(s) in a first plane; obtaining a second image data volume from a second image(s) in a second plane; combining the image data; and using the combined image data to derive an implant shape. In view of the amendments to claim 11 deleting the requirement of boundary image data extraction and combination, Applicants submit that the rejection is moot as to claims 11-17. The rejection is respectfully submit to be moot as to claim 21; amended claim 18, from which claim 21

depends, also does not require boundary image data extraction and combination. Withdrawal of the rejection is therefore requested.

Applicants traverse the rejection of claim 33. In the Office Action, the Examiner, with respect to original claim 11, pointed to Aylward as teaching "extracting boundary image data from each of the first and second image data volumes…; and, combining the extracted boundary image data to form a resultant image data volume..." He concluded that it would have been "obvious to one of ordinary skill in the art at the time the invention was made to use extracting a boundary image data volume as taught by Aylward in the system of Webber because Aylward provides Webber an improved for stable, accurate, and fast representation and analysis of tubular objects in multi-dimensional images." Aylward was applied in this manner to now-cancelled claim 10 also. Since amended claim 26, from which claim 33 depends, recites a method for treating a body part comprising: acquiring at least a first data volume and a second data volume from at least a first body part image and a second body part image, wherein the first body part image is obtained in a first plane and the second body part image is obtained in a second plane and further wherein the first plane is not equal to the second plane; extracting boundary image data from each of the data volumes; combining the extracted boundary image data to form a resultant boundary data volume; deriving the three-dimensional shape of the body part from the resultant boundary data volume; and selecting a therapy utilizing the three-dimensional shape information, Applicants provide the following comments regarding Aylward vis-à-vis Applicants' claim 26 and its dependents.

Amended claim 26 and its dependents relates to an embodiment of image analysis methods disclosed in Applicants' specification wherein first and second

image data volumes are generated from first and second body part images obtained in unequal first and second planes; boundary image data is extracted from each of the first and second image data volumes; the extracted boundary image data is combined to form a resultant boundary data volume; and the three-dimensional shape of the body part is derived from the resultant boundary data volume, and a therapy is further selected from the 3-D shape information. Due to the combination of the boundary image data from the two data volumes (not just the extraction of boundary image data), the resultant boundary data volume has increased resolution at its edges. Such high resolutions previously required tradeoffs like longer scan times, thus the claimed embodiments represent a significant benefit to practitioners in the art, *e.g.*, in designing joint implants having a three-dimensional surface of superior fidelity.

Aylward's teachings cited by the Examiner (italicized) appear in their original context below:

> "Methods of rapidly rendering vessel representations can be achieved by viewing each vessel point as a sphere and by: 1) front projection of each vessel's skeleton points onto a modified z-buffer that also records the vessel identification number, the point identification number, and the radius of the point, 2) if perspective projection is used, calculation of the length of the projected radius on the view-plane for each projected point, 3) creation of a circle on the view-plane for each projected point, and 4) back-projecting rays only through the indicated sphere of interest. *If desired, possibly creating "fuzzy" extraction boundaries allowing more of the image data to*

be seen by arbitrarily multiplying the radius by any desired value." (column 24, lines 16-19)

"Another embodiment of the invention limits automatic seed point determination to search spaces confined to the space just beyond the surface of each tubular object already extracted. *The user first specifies a tubular object to be extracted using the manual approach described above. All seed points in the vicinity of the extracted tube will be automatically identified by searching the space confined to the tube. Subsequent processing steps will automatically extract all tubular objects that abut the initially extracted tubular object. Once again, stricter tubular extrema criteria are employed to test the candidate seed points to eliminate the extraction of ill-defined tubes. This automated extraction technique combined with a threshold constraint has proven useful for generating representations of vessel trees."* (column 10, lines 33-43)

Firstly (as the Examiner acknowledged with respect to original claim 11), Webber does not teach Applicants' claimed embodiments, nor does it fairly suggest the claimed invention, either. Webber does not teach acquiring at least two data volumes as claimed; extracting boundary image data from each of the data volumes; combining the extracted boundary image data to form a resultant boundary data volume; deriving the three-dimensional shape of the body part from the resultant boundary data volume; and deriving a therapy for the body part using the resultant data volume. Webber in particular does not teach boundary extraction and/or combination; or suggest selecting a therapy for a body part, and is unconcerned with therapy.

One of ordinary skill in the art would also *not* find the claimed embodiment obvious in view of Aylward. Respectfully, while Aylward does discuss "creating "fuzzy" extraction boundaries", this is not the same thing as what Applicants' claimed embodiment requires, extracting boundary image data from each of the first and second image data volumes, *and* combining the extracted boundary image data to form a resultant boundary data volume. Aylward *does not teach or suggest* extracting boundary image data from image data volumes, *and* combining the extracted boundary image data to form a resultant boundary data volume. Secondly, even *if* this were the case (and Applicants are clearly arguing it is not) there is nothing in Aylward or in Webber that would indicate to one of ordinary skill in the art the desirability of using a boundary image data extraction and combination technique in precisely the same manner as Applicants' claimed embodiments; to form an image data volume of the extracted boundary image data, *and* that the benefits of the claimed embodiments as noted above (shorter scan times *and* higher resolution at the edges of the boundary image data), would result.

The combination of boundary image data from the data volumes (*not* just the extraction of boundary image data), results in a resultant boundary data volume which has increased resolution at its edges. Obtaining such high resolution previously required undesirable tradeoffs like longer scan times; thus the claimed embodiments represent a significant benefit to practitioners in the art, *e.g.*, in designing joint implants having a three-dimensional surface of superior fidelity. Such attendant benefits were not apparent to one of ordinary skill in the art at the time the present embodiment was made.

In view of the above arguments, Applicants respectfully submit that the claimed embodiments are patentable over the art of record, and respectfully request withdrawal of the rejection of claim 33.

Claims 34 and 38 were rejected under 35 U.S.C. §103(a) as unpatentable (obvious) over Webber, in view of Bonutti U.S. Patent No. 6,702,821 ("Bonutti", or " '821 "). The rejection is moot as to canceled claim 34. As to claim 38, Applicants respectfully traverse.

Claim 38 recites methods for designing implants, including acquiring at least two data volumes from at least two body part images performed in two different planes; combining the data volumes to form a resultant data volume; deriving the three-dimensional shape of the body part from the resultant data volume; and deriving an implant shape utilizing the three-dimensional shape information.

Bonutti was said to disclose instrumentation "for minimally invasive joint replacement and methods for using same comprising: the step of deriving an implant shape utilizing the resultant data volume (column 51, lines 31-36)." Bonutti certainly does disclose robotic instrumentation for performing joint surgery in great detail, but the reference does not teach or suggest at all designing or deriving an implant shape using imaging data as Applicants do, and certainly not in the manner as claimed by Applicants, or as urged by the Examiner. The passage of Bonutti cited by the Examiner:

> "The implant 626 may be formed to have any one of a plurality of different sizes and configurations. The implant may be shaped to the desired configuration at a location remote from an operating room and transported to the operating room.

> Alternatively, the implant 626 could be cut to the desired shape in the operating room."

is completely aspirational; and only states that an implant *may* be formed to have *any* size or configuration, not that it be made to any *specific* dimensions or shape – such as is claimed by Applicants. The teachings of Bonutti cannot be fairly said to convey to one of ordinary skill in the art a "step of deriving an implant shape utilizing (a) resultant data volume" as claimed, and as such are respectfully submitted to be insufficient to, in combination with Webber, render the claimed embodiment obvious. Withdrawal of the rejection is in order.

Claims 35-37 and 39-41 were rejected under 35 U.S.C. §103(a) as unpatentable (obvious) over Webber and Bonutti as applied to claims 34 and 38, and further in view of Thesen. The rejection is moot as to canceled claims 35-37 and 39-40. Applicants respectfully traverse the rejection of claim 41, applying the arguments made hereinabove to the combination of Webber and Bonutti against claim 38, to which claim 41 depends; and to Webber and Thesen. Neither Bonutti or Thesen supply any teaching or suggestion to Webber's teachings to render the claimed embodiment obvious, and withdrawal of the rejection of claim 41 is believed to be in order.

CONCLUSION

It is believed that the application is in condition for allowance. Consideration of the application and issuance of a notice of allowance are respectfully requested.

Applicants request that the undersigned, Alexander J. Smolenski, Jr., be contacted if it will assist further examination of this application.

Respectfully submitted,

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